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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,075	03/19/2004	Jeffrey D. Johnson	016325-008110US	7921
20350 7590 02/22/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER

1635

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/805,075	Applicant(s) JOHNSON ET AL.	
	Examiner Kimberly Chong	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 23 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 23 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/1/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group VII, claims 21, 23 and 34-37 in the reply filed on 4 December 2006 is acknowledged.

Status of the Application

Claims 1-21, 23, and 34-37 are pending. Claims 21, 23 and 34-37 are currently under examination. Claims 1-20 are withdrawn as being drawn to a non-elected invention and claims 22 and 24-33 are canceled.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 11 February 2005 is in compliance with 37 CFR 19.7. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Specification: Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because the drawings listed as 2a, 2b and 2c recite amino acid sequences that are not identified by the required sequence identifier in either the drawings or the brief description of the drawings, on page 5 and 6 of the specification.

A complete response to this office action must correct the defects cited above regarding compliance with the sequence rules and a response to the action on the merits which follows.

The aforementioned instance of failure to comply is not intended as an exhaustive list of all such potential failures to comply in the instant application. Applicants are encouraged to thoroughly review the application to ensure that the entire application is in full compliance with all sequence rules. This requirement will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 23 and 34-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are drawn to a method of identifying an agent for treating a diabetic or pre-diabetic individual wherein the method comprising contacting a candidate agent with a polypeptide having glucose phosphorylating activity that comprises at least 20 contiguous amino acids of SEQ ID NO. 2 and then determining the binding of the agent to the polypeptide, then selecting an agent that decrease the activity of the polypeptide, administering the agent to a diabetic or pre-diabetic animal,

determining the response to the animal to glucose and select an agent that improves the response to glucose.

It is unclear to one of skill in the art that "an agent" recited in step (vi) of claim 21 refers to the same agent that was selected in step (iii) and subsequently administered to a diabetic or pre-diabetic animal. Applicant should correct step (vi) to recite "the agent" to clarify that the agent in step (vi) is the same agent referred to in the previous method steps of claim 21.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21 and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyers et al. (US 2002/0009779).

The instant claims are drawn to a method of identifying an agent for treating a diabetic or pre-diabetic individual, the method comprising contacting a candidate agent with a polypeptide having glucose phosphorylating activity that comprises at least 20 contiguous amino acids of SEQ ID NO. 2, determining the binding of the agent to the polypeptide, selecting an agent that decrease the activity of the polypeptide, administering the agent to a diabetic or pre-diabetic animal, determining the response to the animal to glucose and select an agent that improves the response to glucose. The

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claims are further drawn the polypeptide comprising SEQ ID NO. 2 and wherein the contacting step comprises contacting a cell that expresses the polypeptide or an expression vector.

Meyers et al. teach a method of identifying candidate test compounds or agents which bind to a polypeptide having glucose phosphorylating activity, identified as 50365 polypeptide (see paragraph 0224). The 50365 polypeptide taught by Meyers et al. teach is identical to the instantly claimed polypeptide having SEQ ID NO. 2 and therefore comprises SEQ ID NO. 2 (see attached sequence search: Result 1 in rapbm database). Meyers et al. teach a host cell comprising said polypeptide and further teach an expression vector comprising said polypeptide (see paragraph 0007). Meyers et al. teach binding of said candidate test compound or agent with the 50365 polypeptide and determining whether the test compound or agent binds to said polypeptide by assaying for the 50365 activity (see paragraph 0224-0226) wherein said contacting of said candidate agent with the 50365 polypeptide occurs in a host cell expressing said polypeptide (see paragraph 0230). Meyers et al. teach said candidate test compounds or agents can comprise antisense nucleic molecules, ribozymes or antibodies that bind to the 50365 polypeptide (see paragraphs 0118-0191). Meyers et al. teach a method of administering said agent, identified as capable of binding and modulating expression of 50365 polypeptide, to a subject at risk of a disorder or having a disorder associated with increased expression of said 50365 polypeptide and preventing in a subject, said disorder wherein the disorder is diabetes (see paragraph 0379-0382 and 0392 and 0068). The method of preventing diabetes in a subject would meet the limitation of

determining the response of the animal to glucose since glucose metabolism and modulation thereof is directly related to diabetes (see paragraph 0055-0057 and 0068).

Thus, the Meyers et al. anticipates claims 21 and 34-36 of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 23 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers et al. (US 20020009779) and Liang et al. (J. of Biological Chemistry, 1990. Vol. 265: 16863-16866).

Meyers et al. is relied upon as in the 35 U.S.C. 102(b) rejection above. Meyers et al. do not teach the step of determining the response of an animal to glucose comprising determining the level of glucose-induced insulin and do not teach contacting a pancreatic islet cell with a candidate agent.

Liang et al. teach isolating pancreatic islet cells and a method of determining the level of glucose-induced insulin secretion in pancreatic cells (see Figure 1).

It would have been obvious to one of skill in the art to use the method of determining the level of glucose-induced insulin secretion, as taught by Liang et al. in the method of identifying a candidate agent that regulates glucose metabolism as claimed. It would have further been obvious to one of skill in the art to use a pancreatic

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islet cell in the methods of identifying a candidate agent that regulates glucokinase activity.

One of skill in the art would have been motivated to determine the response of the animal to glucose using the method taught by Liang et al. because Liang et al. teach glucose is an important determinant of glucokinase activity i.e. hexokinase activity, in pancreatic cells (see page 16865) and because the activity of glucokinase plays a crucial role in metabolic disorders involving glucose, such as diabetes, it would be important to monitor the response of glucose. One of skill in the art would have further been motivated to determine the level of glucose-induced insulin secretion after treatment of cells with an agent that binds to a glucokinase to further determine the candidate agent's ability to regulate glucose and as taught by Liang et al., determining the role of glucokinase is important in the metabolism-dependent process of insulin synthesis (see past paragraph page 16866). Moreover, one of skill in the art would have been motivated to use a pancreatic cell in the instantly claimed method since pancreatic islet cells secrete insulin and because insulin is directly regulated by glucose, the islet cells would be an important cell to determine the response to glucose in diabetic or pre-diabetic subjects.

One would have had a reasonable expectation of success given Meyers et al. teach a method of identifying any candidate test compound or agent that regulates a glucokinase activity, such as 50365 polypeptide, and teach said polypeptide has a role in diabetes. One would have had a reasonable expectation of such given that Liang et al. teach the relationship between glucose metabolism and glucokinase and teach a

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method of isolating islet cells and determining the modulation of insulin in response to glucose metabolism by glucokinase.

Thus, in the absence of evidence to the contrary, the invention is *prima facie* obvious to one of skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong
Examiner
Art Unit 1635



SEAN MCGARRY
PRIMARY EXAMINER